IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FOREST LABORATORIES, LLC, FOREST LABORATORIES HOLDINGS, LTD., and ADAMAS PHARMACEUTICALS, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
LUPIN LIMITED, LUPIN PHARMACEUTICALS, INC., PAR PHARMACEUTICAL, INC., ANCHEN PHARMACEUTICALS, INC., AMERIGEN PHARMACEUTICALS, INC., and AMERIGEN PHARMACEUTICALS LTD.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Forest Laboratories, LLC (f/k/a Forest Laboratories, Inc.), Forest Laboratories Holdings, Ltd., and Adamas Pharmaceuticals, Inc. (collectively, "Plaintiffs"), for their Complaint against Defendants Lupin Limited, Lupin Pharmaceuticals, Inc., Par Pharmaceutical, Inc., Anchen Pharmaceuticals, Inc., Amerigen Pharmaceuticals, Inc., and Amerigen Pharmaceuticals Ltd. (collectively, "Defendants"), hereby allege as follows.

PARTIES

1. Plaintiff Forest Laboratories, LLC (f/k/a Forest Laboratories, Inc.) is a Delaware limited liability company having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

2. Plaintiff Forest Laboratories Holdings, Ltd. is an Irish corporation having a principal place of business at Columbia House, 1 Victoria Street, Hamilton HM11, Bermuda (referred to herein, together with Forest Laboratories, Inc., as "Forest").

3. Plaintiff Adamas Pharmaceuticals, Inc. ("Adamas") is a Delaware corporation having a principal place of business at 2200 Powell Street, Suite 220, Emeryville, California 94608.

4. Upon information and belief, Defendant Lupin Limited is an Indian corporation having a principal place of business at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (East), Mumbai, Maharashtra 400 051, India. Upon information and belief, Defendant Lupin Limited manufactures and/or distributes numerous generic drugs for sale and use throughout the United States, including in this judicial district, and including through its subsidiary and agent Lupin Pharmaceuticals, Inc.

5. Upon information and belief, Defendant Lupin Pharmaceuticals, Inc. is a Virginia corporation having a principal place of business at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202. Upon information and belief, Defendant Lupin Pharmaceuticals, Inc. (referred to herein, together with Lupin Limited, as "Lupin") manufactures and/or distributes numerous generic drugs for sale and use throughout the United States, including in this judicial district, and including as a subsidiary and agent of Lupin Limited.

6. Upon information and belief, Defendant Par Pharmaceutical, Inc. ("Par") is a Delaware corporation having a principal place of business at One Ram Ridge Road, Spring Valley, NY 10977. Upon information and belief, Defendant Par Pharmaceutical, Inc. manufactures and/or distributes numerous generic drugs for sale and use throughout the United States, including in this judicial district, and including through its subsidiary and agent Anchen Pharmaceuticals, Inc.

7. Upon information and belief, Defendant Anchen Pharmaceuticals, Inc. ("Anchen") is a California corporation having a principal place of business at 9601 Jeronimo

Road, Irvine, California 92618. Upon information and belief, Defendant Anchen Pharmaceuticals, Inc. manufactures and/or distributes numerous generic drugs for sale and use throughout the United States, including in this judicial district, and including as a subsidiary and agent of Par Pharmaceutical, Inc.

8. Upon information and belief, Defendant Amerigen Pharmaceuticals, Inc. is a Delaware corporation having a principal place of business at 9 Polito Avenue, Suite 900, Lyndhurst, New Jersey, 07071. Upon information and belief, Defendant Amerigen Pharmaceuticals, Inc. manufactures and/or distributes numerous generic drugs for sale and use throughout the United States, including in this judicial district, and including as an agent for Amerigen Pharmaceuticals Ltd.

9. Upon information and belief, Defendant Amerigen Pharmaceuticals Ltd. is a Cayman Islands corporation having a registered office at C/O Codan Trust Company (Cayman) Limited, Cricket Square, Hutchins Drive, P.O. Box 2681, Grand Cayman, KY1-1111 Cayman. Upon information and belief, Defendant Amerigen Pharmaceuticals Ltd. (referred to herein, together with Amerigen Pharmaceuticals, Inc. as "Amerigen") manufactures and/or distributes numerous generic drugs for sale and use throughout the United States, including in this judicial district, and including through its agent Amerigen Pharmaceuticals, Inc.

NATURE OF THE ACTION

10. This is a civil action for the infringement of one or more of the following patents by each of the Defendants: United States Patent Nos. 8,039,009 ("the '009 patent"), 8,168,209, as corrected ("the '209 patent"); 8,173,708 ("the '708 patent"); 8,283,379 as corrected ("the '379 patent"); 8,329,752 ("the '752 patent"); 8,362,085 ("the '085 patent"); and 8,598,233 ("the '233 patent"). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

JURISDICTION AND VENUE

11. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

12. This Court has personal jurisdiction over each of the Defendants by virtue of the fact that, *inter alia*, each Defendant has committed, or aided, abetted, induced, contributed to, and/or participated in the commission of, a tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs in Delaware. This Court has personal jurisdiction over each of the Defendants for the additional reasons set forth below and for other reasons that will be presented to the Court if such personal jurisdiction is challenged.

13. This Court has personal jurisdiction over Defendant Lupin Limited by virtue of, *inter alia*: (1) its presence in Delaware, including through its subsidiary and agent Defendant Lupin Pharmaceuticals, Inc.; and (2) its systematic and continuous contacts with Delaware, including through its subsidiary and agent Lupin Pharmaceuticals, Inc. On information and belief, Lupin Limited is amenable to litigating in this forum based on Lupin Limited's conduct in multiple prior litigations in this District. In particular, Lupin Limited did not contest jurisdiction in Civil Action No. 14-184 (D.I. 28) or Civil Action No. 13-1604 (D.I. 11).

14. This Court has personal jurisdiction over Defendant Lupin Pharmaceuticals, Inc. by virtue of, *inter alia*: (1) its presence in Delaware, including through its parent Defendant Lupin Limited; and (2) its systematic and continuous contacts with Delaware, including through its parent Lupin Limited. On information and belief, Lupin Pharmaceuticals, Inc. is amenable to litigating in this forum based on Lupin Pharmaceuticals, Inc.'s conduct in multiple prior litigations in this District. In particular, Lupin Pharmaceuticals, Inc. did not contest jurisdiction in Civil Action No. 14-184 (D.I. 28) or Civil Action No. 13-1604 (D.I. 11).

15. This Court has personal jurisdiction over Defendant Par Pharmaceutical, Inc. by virtue of, *inter alia*, the fact that Par Pharmaceutical, Inc. is a Delaware corporation.

16. This Court has personal jurisdiction over Defendant Anchen Pharmaceuticals, Inc. by virtue of, *inter alia*: (1) its presence in Delaware, including through its parent Defendant Par Pharmaceutical, Inc.; and (2) its systematic and continuous contacts with Delaware, including through its parent Par Pharmaceutical, Inc. On information and belief, Anchen Pharmaceuticals, Inc. is amenable to litigating in this forum based on Anchen Pharmaceuticals, Inc.'s conduct in multiple prior litigations in this District. In particular, Anchen Pharmaceuticals, Inc. did not contest jurisdiction in this District in Civil Action No. 14-200 (D.I. 26) (related case), Civil Action No. 13-202 (D.I. 15) or Civil Action No. 12-808 (D.I. 13).

17. This Court has personal jurisdiction over Defendant Amerigen Pharmaceuticals, Inc. by virtue of, *inter alia*, the fact that Amerigen Pharmaceuticals, Inc. is a Delaware corporation.

18. This Court has personal jurisdiction over Defendant Amerigen Pharmaceuticals Ltd. by virtue of, *inter alia*: (1) its presence in Delaware, including through its agent Defendant Amerigen Pharmaceuticals, Inc.; and (2) its systematic and continuous contacts with Delaware, including through its agent Defendant Amerigen Pharmaceuticals, Inc. On information and belief, Amerigen Pharmaceuticals Ltd. is amenable to litigating in this forum based on Amerigen Pharmaceuticals Ltd.'s conduct in multiple prior litigations in this District. In particular, Amerigen Pharmaceuticals Ltd. did not contest jurisdiction in Civil Action No. 14-508 (D.I. 36) (related case), Civil Action No. 13-1156 (D.I. 9) or Civil Action No. 12-305 (D.I. 37).

19. Venue is proper in this judicial district as to all Defendants pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE PATENTS

20. On October 18, 2011, the '009 patent, titled "Modified Release Formulations Of Memantine Oral Dosage Forms," was duly and legally issued by the USPTO. Since the issuance of the '009 patent, Forest Laboratories Holdings, Ltd. has been, and continues to be, the '009 patent's sole owner. A copy of the '009 patent is attached hereto as Exhibit A.

21. On May 1, 2012, the '209 patent, titled "Method And Composition For Administering An NMDA Receptor Antagonist To A Subject," was duly and legally issued by the USPTO. The USPTO issued a certificate of correction for the '209 patent on June 26, 2012. Since the issuance of the '209 patent, Adamas has been, and continues to be, the '209 patent's sole owner. Forest is the exclusive licensee of the '209 patent with respect to commercializing pharmaceutical products containing memantine in the United States. A copy of the '209 patent, including its certificate of correction, is attached hereto as Exhibit B.

22. On May 8, 2012, the '708 patent, titled "Method And Composition For Administering An NMDA Receptor Antagonist To A Subject," was duly and legally issued by the USPTO. Since the issuance of the '708 patent, Adamas has been, and continues to be, the '708 patent's sole owner. Forest is the exclusive licensee of the '708 patent with respect to commercializing pharmaceutical products containing memantine in the United States. A copy of the '708 patent is attached hereto as Exhibit C.

23. On October 9, 2012, the '379 patent, titled "Method And Compositions For The Treatment Of CNS-Related Conditions," was duly and legally issued by the USPTO. The USPTO issued a certificate of correction for the '379 patent on July 8, 2014. Since the issuance of the '379 patent, Adamas has been, and continues to be, the '379 patent's sole owner. Forest is the exclusive licensee of the '379 patent with respect to commercializing pharmaceutical

products containing memantine in the United States. A copy of the '379 patent, including its certificate of correction, is attached hereto as Exhibit D.

24. On December 11, 2012, the '752 patent, titled "Composition For Administering An NMDA Receptor Antagonist To A Subject," was duly and legally issued by the USPTO. Since the issuance of the '752 patent, Adamas has been, and continues to be, the '752 patent's sole owner. Forest is the exclusive licensee of the '752 patent with respect to commercializing pharmaceutical products containing memantine in the United States. A copy of the '752 patent is attached hereto as Exhibit E.

25. On January 29, 2013, the '085 patent, titled "Method For Administering An NMDA Receptor Antagonist To A Subject," was duly and legally issued by the USPTO. Since the issuance of the '085 patent, Adamas has been, and continues to be, the '085 patent's sole owner. Forest is the exclusive licensee of the '085 patent with respect to commercializing pharmaceutical products containing memantine in the United States. A copy of the '085 patent is attached hereto as Exhibit F.

26. On December 3, 2013, the '233 patent, titled "Method For Administering An NMDA Receptor Antagonist To A Subject," was duly and legally issued by the USPTO. Since the issuance of the '233 patent, Adamas has been, and continues to be, the '233 patent's sole owner. Forest is the exclusive licensee of the '233 patent with respect to commercializing pharmaceutical products containing memantine in the United States. A copy of the '233 patent is attached hereto as Exhibit G.

27. Forest Laboratories, Inc. (n/k/a Forest Laboratories, LLC) holds New Drug Application ("NDA") 22-525 for Namenda XR® brand memantine hydrochloride extended release capsules. The '009 patent, the '209 patent, the '708 patent, the '379 patent, the '752 patent,

the '085 patent, and the '233 patent are all listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for Namenda XR®.

28. Forest is the exclusive distributor of Namenda XR® in the United States.

ACTS GIVING RISE TO THIS ACTION

Count I – Patent Infringement by Lupin

29. Upon information and belief, on or before July 22, 2014, Lupin submitted ANDA No. 206028 to the United States Food and Drug Administration ("FDA") under § 505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 206028 seeks FDA approval for the commercial manufacture, use, and sale of generic extended release capsule products containing 7, 14, 21, and 28 milligrams of memantine hydrochloride as the active ingredient ("the Lupin Generic Products"). ANDA No. 206028 specifically seeks FDA approval to market the Lupin Generic Products prior to the expiration of the '009 patent, the '209 patent, the '708 patent, the '379 patent, the '752 patent, the '085 patent, and the '233 patent.

30. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, ANDA No. 206028 alleges that the claims of the '009 patent, the '209 patent, the '708 patent, the '379 patent, the '752 patent, the '085 patent, and the '233 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Lupin Generic Products. Plaintiffs received written notification of ANDA No. 206028 and its § 505(j)(2)(A)(vii)(IV) allegations on or about July 24, 2014.

31. Lupin's submission of ANDA No. 206028 to the FDA, including its § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '209 patent, the '708 patent, the '379 patent, the '752 patent, the '085 patent, and the '233 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Lupin commercially manufactures, uses, offers for sale, or sells

within the United States, or imports into the United States, the Lupin Generic Products, or induces or contributes to any such conduct, it would further infringe the '209 patent, the '708 patent, the '379 patent, the '752 patent, the '085 patent, and/or the '233 patent under 35 U.S.C. § 271(a), (b), and/or (c). For purposes of clarity, Plaintiffs state that they are not asserting Claims 6-15 of the '379 patent against the Lupin Generic Products or any other generic extended release memantine hydrochloride product that contains memantine hydrochloride as the sole active ingredient. Relying on the representations set out in Lupin's notice of Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95, Plaintiffs do not allege at this time that the Lupin Generic Products infringe the '009 patent. To the extent that discovery in this action demonstrates that assertion of the '009 patent against the Lupin Generic Products is warranted, Plaintiffs reserve the right to assert it.

32. Upon information and belief, each of Lupin Limited and Lupin Pharmaceuticals, Inc. has participated in, contributed to, aided, abetted, and/or induced infringement of the '209 patent, the '708 patent, the '379 patent, the '752 patent, the '085 patent, and/or the '233 patent and/or will participate in, contribute to, aid, abet, and/or induce infringement of the '209 patent, the '708 patent, the '379 patent, the '752 patent, the '085 patent, and/or the '233 patent once the Lupin Generic Products are manufactured, used, offered for sale, or sold in the United States, or imported into the United States. Each of Lupin Limited and Lupin Pharmaceuticals, Inc. is jointly and severally liable for the infringement of the '209 patent, the '708 patent, the '379 patent, the '752 patent, the '085 patent, and/or the '233 patent.

33. Lupin was aware of the '209 patent, the '708 patent, the '379 patent, the '752 patent, and the '085 patent prior to filing ANDA No. 206028, including its

§ 505(j)(2)(A)(vii)(IV) allegations with respect to those patents, and was aware of the '233 patent at least prior to making its § 505(j)(2)(A)(vii)(IV) allegation with respect to that patent.

34. Lupin's actions render this an exceptional case under 35 U.S.C. § 285.

35. Plaintiffs will be irreparably harmed by Lupin's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Count II – Patent Infringement by Anchen and Par

36. Upon information and belief, on or before January 6, 2014, Anchen and Par submitted ANDA No. 205784 to the FDA under § 505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 205784 seeks FDA approval for the commercial manufacture, use, and sale of generic extended release capsule products containing 28 milligrams of memantine hydrochloride as the active ingredient ("the Anchen Generic Product").

37. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, ANDA No. 205784 previously included allegations that the claims of the '009 patent, the '209 patent, the '708 patent, the '379 patent, the '752 patent, and the '085 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Anchen Generic Product. Plaintiffs received written notification of ANDA No. 205784 and its previous § 505(j)(2)(A)(vii)(IV) allegations with respect to the '009 patent, the '209 patent, the '708 patent, the '379 patent, the '752 patent, and the '085 patent on or about January 7, 2014. The written notification also stated that ANDA No. 205784 contained a § 505(j)(2)(A)(vii)(IV) allegation that the claims of the '233 patent are invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of the Anchen Generic Product. Plaintiffs timely brought suit against Anchen and Par for infringement of the '209 patent, the '708 patent, the '379 patent, the '752

patent, the '085 patent, and the '233 patent on or about February 14, 2014 in *Forest Laboratories, Inc., et al. v. Apotex Corp., et al.*, Civil Action No. 14-200-LPS.

38. Upon information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, ANDA No. 205784 was recently amended to include an allegation that the claims of the '233 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Anchen Generic Product. Upon information and belief, prior to this amendment, ANDA No. 205784 did not include a § 505(j)(2)(A)(vii)(IV) allegation with respect to the '233 patent, contrary to Anchen and Par's representation in the written notification received on or about January 7, 2014. Plaintiffs received written notification of Anchen and Par's amended § 505(j)(2)(A)(vii)(IV) allegation with respect to the '233 patent on or about July 7, 2014.

39. Anchen and Par's submission of ANDA No. 205784 to the FDA, including their recent § 505(j)(2)(A)(vii)(IV) allegation with respect to the '233 patent, constitutes infringement of the '233 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Anchen and Par commercially manufacture, use, offer for sale, or sell within the United States, or import into the United States, the Anchen Generic Product, or induce or contribute to any such conduct, they would further infringe the '233 patent under 35 U.S.C. § 271(a), (b), and/or (c).

40. Upon information and belief, each of Anchen and Par has participated in, contributed to, aided, abetted, and/or induced infringement of the '233 patent and/or will participate in, contribute to, aid, abet, and/or induce infringement of the '233 patent once the Anchen Generic Product is manufactured, used, offered for sale, or sold in the United States, or imported into the United States. Each of Anchen and Par is jointly and severally liable for the infringement of the '233 patent.

41. Anchen and Par were aware of the '233 patent at least prior to making their § 505(j)(2)(A)(vii)(IV) allegation with respect to that patent.

42. Anchen and Par's actions render this an exceptional case under 35 U.S.C. § 285.

43. Plaintiffs will be irreparably harmed by Anchen and Par's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Count III – Patent Infringement by Par

44. Upon information and belief, on or before January 29, 2014, Par submitted ANDA No. 205783 to the FDA under § 505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 205783 seeks FDA approval for the commercial manufacture, use, and sale of generic extended release capsule products containing 28 milligrams of memantine hydrochloride as the active ingredient ("the Par Generic Product").

45. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, ANDA No. 205783 previously included allegations that the claims of the '009 patent, the '209 patent, the '708 patent, the '379 patent, the '752 patent, and the '085 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Par Generic Product. Plaintiffs received written notification of ANDA No. 205783 and its previous § 505(j)(2)(A)(vii)(IV) allegations with respect to the '009 patent, the '209 patent, the '708 patent, the '379 patent, the '752 patent, and the '085 patent on or about January 30, 2014. The written notification also stated that ANDA No. 205783 contained a § 505(j)(2)(A)(vii)(IV) allegation that the claims of the '233 patent are invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of the Par Generic Product. Plaintiffs timely brought suit against Par for infringement of the '009 patent, the '209 patent, the '708 patent, the '379 patent, the '752

patent, the '085 patent, and the '233 patent on or about February 14, 2014 in *Forest Laboratories, Inc., et al. v. Apotex Corp., et al.*, Civil Action No. 14-200-LPS.

46. Upon information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, ANDA No. 205783 was recently amended to include an allegation that the claims of the '233 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Par Generic Product. Upon information and belief, prior to this amendment, ANDA No. 205783 did not include a § 505(j)(2)(A)(vii)(IV) allegation with respect to the '233 patent, contrary to Par's representation in the written notification received on or about January 30, 2014. Plaintiffs received written notification of Par's amended § 505(j)(2)(A)(vii)(IV) allegation with respect to the '233 patent on or about July 7, 2014.

47. Par's submission of ANDA No. 205783 to the FDA, including its recent § 505(j)(2)(A)(vii)(IV) allegation with respect to the '233 patent, constitutes infringement of the '233 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Par commercially manufactures, uses, offers for sale, or sells within the United States, or imports into the United States, the Par Generic Product, or induces or contributes to any such conduct, it would further infringe the '233 patent under 35 U.S.C. § 271(a), (b), and/or (c).

48. Par was aware of the '233 patent at least prior to making its § 505(j)(2)(A)(vii)(IV) allegation with respect to that patent.

49. Par's actions render this an exceptional case under 35 U.S.C. § 285.

50. Plaintiffs will be irreparably harmed by Par's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Count IV – Patent Infringement by Amerigen

51. Upon information and belief, on or before March 31, 2014, Amerigen submitted ANDA No. 205365 to the FDA under § 505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) seeking FDA approval for the commercial manufacture, use, and sale of generic extended release capsule products containing 7, 14, and 28 milligrams of memantine hydrochloride as the active ingredient ("the Amerigen Generic Products"). ANDA No. 205365 specifically seeks FDA approval to market the 7, 14, and 28 milligram dosage forms of the Amerigen Generic Products prior to the expiration of the '009 patent, the '209 patent, the '708 patent, the '379 patent, the '752 patent, the '085 patent, and the '233 patent.

52. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, ANDA No. 205365 includes allegations that the claims of the '009 patent, the '209 patent, the '708 patent, the '379 patent, the '752 patent, the '085 patent, and the '233 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the 7, 14, and 28 milligram dosage forms of the Amerigen Generic Products. Forest and Adamas received written notification of ANDA No. 205365 and its § 505(j)(2)(A)(vii)(IV) allegations on or about April 1, 2014. Plaintiffs timely brought suit against Amerigen for infringement of the '009 patent, the '209 patent, the '708 patent, the '379 patent, the '752 patent, the '085 patent, and the '233 patent on or about April 21, 2014 in *Forest Laboratories, Inc., et al. v. Amneal Pharmaceuticals LLC, et al.*, Civil Action No. 14-508-LPS.

53. On or about August 6, 2014, Forest and Adamas received written notification that Amerigen had amended ANDA No. 205365 to include a 21 milligram dosage form of the Amerigen Generic Products. As amended, ANDA No. 205365 seeks FDA approval for the commercial manufacture, use, and sale of generic extended release capsule products containing

21 milligrams of memantine hydrochloride as the active ingredient. ANDA No. 205365 specifically seeks FDA approval to market the 21 milligram dosage form of the Amerigen Generic Products prior to the expiration of the '009 patent, the '209 patent, the '708 patent, the '379 patent, the '752 patent, and the '085 patent.

54. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, ANDA No. 205365 alleges that the claims of the '009 patent, the '209 patent, the '708 patent, the '379 patent, the '752 patent, and the '085 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the 21 milligram dosage form of the Amerigen Generic Products.

55. Amerigen's submission of its amendment to ANDA No. 205365 to the FDA, including its § 505(j)(2)(A)(vii)(IV) allegations regarding the 21 milligram dosage form of the Amerigen Generic Products, constitutes infringement of the '009 patent, the '209 patent, the '708 patent, the '379 patent, the '752 patent, and the '085 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Amerigen commercially manufactures, uses, offers for sale, or sells within the United States, or imports into the United States, the 21 milligram dosage form of the Amerigen Generic Products, or induces or contributes to any such conduct, it would further infringe the '009 patent, the '209 patent, the '708 patent, the '379 patent, the '752 patent, and the '085 patent under 35 U.S.C. § 271(a), (b), and/or (c). For purposes of clarity, Forest and Adamas state that they are not asserting Claims 6-15 of the '379 patent against the 21 milligram dosage form of the Amerigen Generic Products or any other generic extended release memantine hydrochloride product that contains memantine hydrochloride as the sole active ingredient.

56. Upon information and belief, each of Amerigen Pharmaceuticals, Inc. and Amerigen Pharmaceuticals Ltd. has participated in, contributed to, aided, abetted, and/or induced

infringement of the '009 patent, the '209 patent, the '708 patent, the '379 patent, the '752 patent, and the '085 patent and/or will participate in, contribute to, aid, abet, and/or induce infringement of the '009 patent, the '209 patent, the '708 patent, the '379 patent, the '752 patent, and the '085 patent once the 21 milligram dosage form of the Amerigen Generic Products is manufactured, used, offered for sale, or sold in the United States, or imported into the United States. Each of Amerigen Pharmaceuticals, Inc. and Amerigen Pharmaceuticals Ltd. is jointly and severally liable for the infringement of the '009 patent, the '209 patent, the '708 patent, the '379 patent, the '752 patent, and the '085 patent.

57. Amerigen was aware of the '009 patent, the '209 patent, the '708 patent, the '379 patent, the '752 patent, and the '085 patent at least prior to filing its amendment to ANDA No. 205365, including its § 505(j)(2)(A)(vii)(IV) allegations with respect to those patents.

58. Amerigen's actions render this an exceptional case under 35 U.S.C. § 285.

59. Forest and Adamas will be irreparably harmed by Amerigen's infringing activity unless those activities are enjoined by this Court. Forest and Adamas do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. That Defendant Lupin has infringed the '209 patent, the '708 patent, the '379 patent, the '752 patent, the '085 patent, and the '233 patent;

B. That Defendants Anchen and Par have infringed the '233 patent;

C. That Defendant Par has infringed the '233 patent;

D. That Defendant Amerigen has infringed the '009 patent, the '209 patent, the '708 patent, the '379 patent, the '752 patent, and the '085 patent;

E. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Defendant Lupin's ANDA identified in this Complaint shall not be earlier than the expiration date of the last to expire of the '209 patent, the '708 patent, the '379 patent, the '752 patent, the '085 patent, and the '233 patent, including any extensions or exclusivities;

F. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Defendants Anchen and Par's ANDA No. 205784 shall not be earlier than at least the expiration date of the '233 patent, including any extensions or exclusivities;

G. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Defendant Par's ANDA 205783 shall not be earlier than at least the expiration date of the '233 patent, including any extensions or exclusivities;

H. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Defendant Amerigen's ANDA No. 205365 for the 21 milligram dosage form of the Amerigen Generic Products shall not be earlier than the expiration date of the last to expire of the '009 patent, the '209 patent, the '708 patent, the '379 patent, the '752 patent, and the '085 patent, including any extensions or exclusivities;

I. That Defendant Lupin, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, are preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale, or selling in the United States, or importing into the United States, the Lupin Generic Products, and any other product that infringes or induces or contributes to the infringement of the '209 patent, the '708 patent, the '379 patent, the '752 patent, the '085 patent, or the '233 patent prior to the expiration date of the last to expire of those patents, including any extensions or exclusivities;

J. That Plaintiffs be awarded monetary relief if Defendant Lupin commercially makes, uses, offers for sale, or sells in the United States, or imports into the United States, the Lupin Generic Products, or any other product that infringes or induces or contributes to the infringement of the '209 patent, the '708 patent, the '379 patent, the '752 patent, the '085 patent, or the '233 patent prior to the expiration of the last to expire of those patents, including any extensions or exclusivities, and that such monetary relief be awarded to Plaintiffs with prejudgment interest;

K. That Defendants Anchen and Par, their officers, agents, servants, and employees, and those persons in active concert or participation with any of them, are preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale, or selling in the United States, or importing into the United States, the Anchen Generic Product, and any other product that infringes or induces or contributes to the infringement of the '233 patent, prior to the expiration date of that patent, including any extensions or exclusivities;

L. That Plaintiffs be awarded monetary relief if Defendants Anchen and Par commercially make, use, offer for sale, or sell in the United States, or import into the United States, the Anchen Generic Product, or any other product that infringes or induces or contributes to the infringement of the '233 patent, prior to at least the expiration date of that patent, including any extensions or exclusivities, and that such monetary relief be awarded to Plaintiffs with prejudgment interest;

M. That Defendant Par, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, are preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale, or selling in the United States, or importing into the United States, the Par Generic Product, and any other product that

infringes or induces or contributes to the infringement of the '233 patent, prior to the expiration date of that patent, including any extensions or exclusivities;

N. That Plaintiffs be awarded monetary relief if Defendant Par commercially makes, uses, offers for sale, or sells in the United States, or imports into the United States, the Par Generic Product, or any other product that infringes or induces or contributes to the infringement of the '233 patent, prior to at least the expiration date of that patent, including any extensions or exclusivities, and that such monetary relief be awarded to Plaintiffs with prejudgment interest;

O. That Defendant Amerigen, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, are preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale, or selling in the United States, or importing into the United States, the 21 milligram dosage form of the Amerigen Generic Products, and any other product that infringes or induces or contributes to the infringement of the '009 patent, the '209 patent, the '708 patent, the '379 patent, the '752 patent, and the '085 patent, prior to the expiration date of those patents, including any extensions or exclusivities;

P. That Plaintiffs be awarded monetary relief if Defendant Amerigen commercially makes, uses, offers for sale, or sells in the United States, or imports into the United States, the 21 milligram dosage form of the Amerigen Generic Products, or any other product that infringes or induces or contributes to the infringement of the '009 patent, the '209 patent, the '708 patent, the '379 patent, the '752 patent, and the '085 patent prior to the expiration of the last to expire of those patents, including any extensions or exclusivities, and that such monetary relief be awarded to Plaintiffs with prejudgment interest;

Q. That Plaintiffs be awarded the attorney fees, costs, and expenses that they incur prosecuting this action under 35 U.S.C. § 285; and

R. That Plaintiffs be awarded such other and further relief as this Court deems just and proper.

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